



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Food and Drug Administration Clinical Trial Requirements, Compliance, and Good Clinical Practice; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Dallas District Office, in co-sponsorship with the Society of Clinical Research Associates (SoCRA) is announcing a public workshop. The public workshop on FDA's clinical trial requirements is designed to aid the clinical research professional's understanding of the mission, responsibilities, and authority of FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA and clinical trial staff, investigators, and institutional review boards (IRBs). Individual FDA representatives will discuss the informed consent process and informed consent documents; regulations relating to drugs, devices, and biologics; as well as inspections of clinical investigators, IRBs, and research sponsors.

Date and Time: The public workshop will be held on March 6 and 7, 2013, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Sheraton Dallas Hotel, 400 North Olive St., Dallas, TX 75201, 214-922-8000. and OMB Control No. 1205-0404

Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of \$145 plus applicable taxes (available until February 3, 2013, or until the SoCRA room block is filled).

Contact: David Arvelo, Office of Regulatory Affairs, Food and Drug Administration, Southwest Regional Office, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214-253-4952, FAX: 214-253-4970, email: david.arvelo@fda.hhs.gov or SoCRA, 530 West Butler Ave., suite 109, Chalfont, PA 18914, 800-762-7292, FAX: 215-822-8633, email: SoCRAmail@aol.com, Web site: <http://www.SoCRA.org>.

Registration: The registration fee covers the cost of actual expenses, including refreshments, lunch, materials, and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. The cost of registration is as follows:

SoCRA member, \$575.00

SoCRA nonmember (includes membership), \$650.00

Federal Government SoCRA member, \$450.00

Federal Government SoCRA nonmember, \$525.00

FDA Employee, Fee Waived

If you need special accommodations due to a disability, please contact SoCRA (see Contact) at least 21 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. SoCRA designates this educational activity for a maximum of 13.3 Continuing Education (CE) credits for SoCRA CE and Nurse continuing nursing education (CNE). SoCRA designates this educational activity for a maximum of 13.3 American Medical Association Physicians Recognition Award Category 1 Credit(s)TM. Physicians should claim credit commensurate with the extent of their participation. SoCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. SoCRA is an approved provider of CNE by the Pennsylvania State Nurses Association (PSNA), an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation (ANCC). ANCC/PSNA Provider Reference Number: 205-3-A-09.

Registration Instructions: To register, please submit a registration form with your name, affiliation, mailing address, phone, fax number, and email, along with a check or money order payable to “SoCRA”. Mail to: SoCRA (see Contact for address). To register via the Internet, go to http://www.socra.org/html/FDA_Conference.htm. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.)

Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the workshop, contact SoCRA (see Contact).

SUPPLEMENTARY INFORMATION: The public conference helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, IRB inspections, electronic record requirements, and investigator initiated research. Topics for discussion include the following: (1) What FDA Expects in a Pharmaceutical Clinical Trial; (2) Adverse Event Reporting--Science, Regulation, Error, and Safety; (3) Part 11 Compliance--Electronic Signatures; (4) Informed Consent Regulations; (5) IRB Regulations and FDA Inspections; (6) Keeping Informed and Working Together; (7) FDA Conduct of Clinical Investigator Inspections; (8) Meetings With FDA: Why, When, and How; (9) Investigator Initiated Research; (10) Medical Device Aspects of Clinical Research; (11) Working With FDA's Center for Biologics Evaluation and Research; (12) The Inspection Is Over--What Happens Next? Possible FDA Compliance Actions; (13) Ethical Issues in Subject Enrollment; (14) Medical Device Aspects of Clinical Research; and (15) Are We There Yet? An Overview of the FDA Good Clinical Practice Program.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The public workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The public workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121) as outreach activities by Government Agencies to small businesses.

Dated: August 8, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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